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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/712,615	11/13/2000	Kenneth F. Buechler	230/006	4653

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EXAMINER	
COOK, LISA V	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 11/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/712,615	BUECHLER ET AL.	
	Examiner	Art Unit	
	Lisa V. Cook	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 August 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27,28 and 93-128* is/are pending in the application.

4a) Of the above claim(s) *113-128* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27,28 and 93-112* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *27,28 and 93-128* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *21* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Amendment Entry

1. Applicant's response to the Office Action mailed 1 May 2003 (Paper #20 filed 8/1/03) is acknowledged. In amendment-E filed therein claims 27, 96, 97, and 105 were modified while new claims 109-128 were added. The newly added claims have been considered and found applicable to Restriction Election Requirements. Currently claims 27, 28, and 93-128 are pending and under consideration.

OBJECTIONS WITHDRAWN

Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the examiner on form PTO-892 or applicant on PTO-1449 has cited the references they have not been considered.

3. The information disclosure statements filed 6/25/01-Paper #6, has not been considered as to the merits prior to first action because the Information Disclosure Statement under 37 CFR 1.56 was not signed. It has been placed in the application file, but the information referred to therein has not been considered as to the merits.

Applicant's IDS filed 8/1/03 in paper #21 has been considered as to the merits before Final Action. The objection regarding the IDS is withdrawn.

REJECTIONS WITHDRAWN

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 27, 28, and 93-128 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

All the claims are directed to device configured to include at least one timing zone. The timing zone allows the device (claim 27) and kit (claim 28) to measure or determine the progress and time of completion of an assay for an analyte of interest in the via the timing zone signal. However support for the "timing zone" is not found in the instant disclosure. Applicant is invited to show support for the "timing zone" in the instant application.

Response to arguments

5. Applicant has shown support for the term "timing zone" in the disclosure. The phrase is cited on page 71 lines 3-5, page 73 line 25, and page 74 line 3 for example. Accordingly the rejection is withdrawn.

NEW OBJECTIONS

6. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, each and every component of the claimed apparatus must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

REJECTIONS MAINTAINED

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

7. Claims 27, 28, and 93-128 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. In claims 27, 28, and 93-128 the use of "timing zone" is vague and indefinite because it is not clear as to what the term is to encompass. Is the zone merely to evaluate the reactions end wherein a signal is evaluated with respect to reagent flow? As recited the term "timing zone" is a relative term, which renders the claim indefinite. The term "timing zone" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

8. Claims 27, 28, and 93-128 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. In claims 27 and 113 the interaction of the "timing zone" is not clear. The apparatus requires two separate zones. Specifically, an assay zone and a timing zone are located on a diagnostic lane wherein a detectable label flows through the diagnostic lane. However the relations between the two individual zones is not recited. It is not clear that the timing zone is located down stream from the assay zone so that it can measure the time of assay completion. Further the label does not clearly bind to either of the zones to produce a detectable product. What binds the detectable label (analyte, IAC,etc), is it already detectable before addition, how does it related to the zones of the diagnostic lane. As recited the label merely flows through the diagnostic lane and does not produce a detectable signal in either the assay zone or the timing zone. Appropriate correction is required.

B. Claims 93, 101, and 115 are vague and indefinite in employing the phrase "and/or" because it is not clear as to how the signal can be electrical and magnetic simultaneously. It is suggested that the claim reads "electrical signal, magnetic signal, and enzyme" in order to obviate this rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 27, 28, and 93-128 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. All the claims are directed to device/apparatus with at least one timing zone separated from the assay zone. The disclosure does not show support form this limitation. For example page 15 lines 19-28 cited by Applicants does not provide support. Therefore the limitation is considered new matter. Applicant is invited to show support for the "timing zone separated from the assay zone" in the instant application.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negative by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

I. Claims 27, 93, 94, 96, 99-100, 109-116, 118, and 121-126 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buechler (U.S. Patent #5,458,852) in view of Van Deusen et al. (U.S. Patent #5,132,097).

Buechler discloses assay devices meeting the requirements of the instant invention. This is supported by the specification on page 59, lines 21-28. Particularly Buechler's device comprises a reaction chamber (column 6) and a diagnostic lane (column 10 –diagnostic element). See figures 1-5, item #4 (reaction chamber, column 6 and 7), item #17 (optional reagent chambers, column 8 and 9, and item # 6 (diagnostic element, column 10). The device includes a time gate for measuring the reaction in a given period of time. Pleas see column 7 lines 41-45.

The device is useful in measuring an absolute signal or a rate of change of the signal. Particularly determining the presence or amount of each target ligand in the sample either visually or instrumentally. Column 17, lines 44-46. The rate of change is monitored via the flow rate of reagents through the porous member. Column 18, lines 2-9. Further the label (signal development element) does not appreciably bind to any reagent in said assay device but could be designed to indirectly cause a visually or instrumentally detectable signal as a result of the assay process. Column 3, lines 17-25.

The apparatus of Buechler further includes an optical system for detecting and processing optical signals generated from the label in the diagnostic lane. Column 20 lines 22-31.

Buechler differs from the instant invention in not specifically disclosing the detailed structure of the optical system including an optical component and a signal processor specifically configured to read electronic signals.

However, such an optical system is considered conventional in the assay art, see Van Deusen et al. Van Deusen et al. teach devices having both an optical signal detector and signal processor. Van Deusen et al. disclose an apparatus for analyzing specific binding complexes. A test strip having a reactive surface coated with a specific binding member is employed and laser analysis allows for detection via a detector assembly (processor). See abstract, Column 2, 55-68 through columns 3, lines 1-6.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to measure optical signals via a signal processor as taught by Van Deusen et al. in the device as taught by Buechler to perform immunoassay detection procedures, because Van Deusen et al. taught that signal processors allowed for information gathering and dissemination. (Column 3, lines 33-35). Further such an optical detector and signal processor are always required in an optical system in order to detect and process the signals generated from the labels.

One having ordinary skill in the art would have been motivated to do this to greatly reduce the time required for analysis and improve reagent flow. Van Deusen Column 3, lines 20 –21.

II. Claims 95 and 117 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buechler (U.S. Patent #5,458,852) in view of Van Deusen et al. as applied to claims 27, 93, 94, 96, 99-100, 109-116, 118, and 121-126 above, and further in view of Slovacek et al. (U.S. Patent#5,242,837).

Please see Buechler (U.S. patent #5,458,852) in view of Van Deusen et al. as set forth above.

The primary references do not particularly exemplify the use of a fluorometer as a useful optical detector.

However, fluorometers are routinely utilized to detect specific binding reagents. This point is supported in the patent of Slovacek et al. Therefor the use of a fluorometer is routine optimizations that are almost always determined and used in immunoassay studies.

Unless the result obtained in the instant application is a significant and unexpected difference over the prior art, it would have been prima facie obvious for one of ordinary skill in the art to employ different known detectors in the given parameters to determine the unknown as a means of optimizing the device provided by the art.

III. Claims 28, 101, 102, 104, 107-108 and 127-128 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buechler (U.S. Patent #5,458,852) in view of Van Deusen et al. as applied to claims 27, 93, 94, 96, 99-100, 109-116, 118, and 121-126 above, and Foster et al. (U.S.Patent#4,444,879).

The teachings of Buechler (U.S. patent #5,458,852) in view of Van Deusen et al. are set forth above. However, these references fail to teach the assay as a kit.

However, kits are well known embodiments for assay reagents. Foster et al. (U.S. Patent #4,444,879) describe one example. In their patent kits including the reactant reagents, a micro plate, positive controls, negative controls, standards, and instructions are taught. See figure 6, and column 15, lines 10-34.

It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to take the detection assay as taught by Buechler (U.S. patent #5,458,852) in view of Van Deusen et al. and format them into a kit because Foster et al. teach that it is convenient to do so and one can enhance sensitivity of a method by providing reagents as a kit. Further, the reagents in a kit are available in pre-measured amounts, which eliminates the variability that can occur when performing the assay.

IV. Claim 103 is rejected under 35 U.S.C. 103(a) as being unpatentable over Buechler (U.S. Patent #5,458,852) in view of Van Deusen et al. and in further view of in view of Foster et al. (U.S.Patent#4,444,879) as applied to claims 28, 101, 102, 104, 107-108 and 127-128 above, and further in view of Slovacek et al. (U.S. Patent#5,242,837).

Please see Buechler (U.S. patent #5,458,852) in view of Van Deusen et al. and in further view of Zuk et al. as set forth above.

The primary references do not particularly exemplify the use of a fluorometer as a useful optical detector.

However, fluorometers are routinely utilized to detect specific binding reagents. This point is supported in the patent of Slovacek et al. Therefor the use of a fluorometer is routine optimizations that are almost always determined and used in immunoassay studies.

Unless the result obtained in the instant application is a significant and unexpected difference over the prior art, it would have been prima facie obvious for one of ordinary skill in the art to employ different known detectors in the given parameters to determine the unknown as a means of optimizing the device provided by the art.

Response to Arguments

11. Applicant argues that the rejection over Buechler et al. in view of Van Deusen et al. fail to establish a prima facie case of obviousness because the rejection does not teach all the elements of the claims. Specifically Applicant contends that the references do not include a "timing zone" wherein an independent assay control signal (IACS) is detected for use in determining if the assay for the analyte of interest has run to completion.

This argument was carefully considered but not found persuasive because the claims do not recite that the "timing zone" includes IACS. As written the timing zone merely has to be apart of the diagnostic lane and separate from the assay zone. No reagents are included in the timing zone to allow for signal generation for detection.

Applicant further contends that the reference of Buechler et al. does not detect any signal whatsoever in the timing zone but measures a resistance that holds the reaction mixture in the reaction chamber for a given period of time (time gate). This argument was carefully considered but not found persuasive because the instant disclosure teaches the same inventive concept with respect to the claimed apparatus.

Specifically the specification teaches that the "assay devices....comprise a time gate control and a flow control". The controls include IAC, which are employed to measure completion by signal generation. See page 60 lines 23-26 for example.

However the cited claims do not include IAC's in the timing zone nor do they clearly set forth that a detectable signal is generated to measure assay completion, therefore there is no requirement for the Buechler et al. reference to teach IAC signal detection.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The rejection is maintained.

Applicant argues that Buechler et al. in view of Van Deusen et al. do not teach a timing zone configured to bind a detectable label, which does not bind appreciably to the assay zone. This argument was carefully considered but not found persuasive because the instant disclosure doe not have support for the aforementioned limitations.

In response to the argument that the primary references fail to teach a processor configured "to determine process and time of completion of an assay from a timing zone", it is noted that it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

With respect to all other claims applicant argues that primary '852 and secondary '097 patents do not teach the instant invention and therefore cannot be combined to teach the other dependent claims. The arguments have been addressed above for primary '852 and secondary '097 patents.

Applicant contends that the patent to May et al. merely teaches sandwich assays and competitive assays but does not read on the instant designed/configured apparatus to practice such assays. This argument was carefully considered and found persuasive. All the rejections including the patent to May et al. (6,187,598) have been withdrawn.

Allowable Subject Matter

12. Claims 97, 98, 105, 106, 119, and 120 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

13. For reasons aforementioned, no claims are allowed.

14. **THIS ACTION IS MADE NON-FINAL.** Examiner apologizes for any inconvenience to Applicant.

Remarks

15. Prior art made of record and not relied upon is considered pertinent to the applicant's disclosure:

A. Davis et al. (EP 0 810 436 A1) disclose solid-phase analytical devices comprising a detection zone and a control zone. See column 6 line 54 through column 7 line 15. The device includes a labeled specific binding reagent (optically detectable label). See abstract. The control zone (applicants timing zone) is configured to convey an unrelated signal with respect to the device completion/success/proper functioning. The control zone is loaded with an antibody that will bind the labeled reagent or an anhydrous reagent that will produce a color change or color formation when moistened (independent of the analyte of interest). In all embodiments it is essential that the labeled reagent migrate/progress with the liquid sample to the detection zone. Column 7 lines 50-58. The device is taught to be configured with separate or distinct zones on the same or different diagnostic lanes (strips, sheets, etc). See column 8 lines 24-53.

16. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 Fax number is (703) 872-9306, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (703) 305-0808. The examiner can normally be reached on Monday-Friday from 8:00 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Lisa V. Cook
CM1-7B17
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10/29/03

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641